IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE INTELLECTUAL PROPERTY MANAGEMENT LIMITED and GLAXOSMITHKLINE LLC (f/k/a SMITHKLINE BEECHAM CORPORATION)	:	
Plaintiffs,	:	
v.	:	C.A. No. 11-1284-RGA
SANDOZ, INC.	:	
Defendant.	:	

CLAIM CONSTRUCTION

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March 20, 2013
Wilmington, Delaware

ANDREWS, UNITED STATES DISTRICT JUDGE:

This is a claim construction opinion. Plaintiffs GlaxoSmithKline Intellectual Property Management Limited and GlaxoSmithKline LLC (collectively "GSK") assert claims against Defendant Sandoz, Inc. for infringement of U.S. Patent Nos. 7,101,866 ("'866 Patent"), 6,858,597 ("'597 Patent") and 7,541,350 ("'350 Patent") in connection with Sandoz's submission of an Abbreviated New Drug Application seeking FDA approval to market a generic version of GSK's Veramyst® product. Veramyst® is an intranasal spray containing a glucocorticoid drug compound and is indicated for treatment of symptoms of seasonal and perennial allergic rhinitis. This opinion construes the single disputed term.

DISCUSSION

Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388–90 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. *Markman*, 52 F.3d at 979. Of these sources, the specification is "always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips v. AWH Corporation*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). However, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.' " *Liebel–Flarsheim Co. v. Medrad*, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (*quoting Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. *Phillips*, 415 F.3d at 1318–19; *Markman*, 52 F.3d at 979–80. However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. *Phillips*, 415 F.3d at 1318–19 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic evidence").

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. *Envirotech Corp. v. Al George, Inc.,* 730 F.2d 753, 759 (Fed. Cir. 1984). If the patent inventor clearly supplies a different meaning, however, then the claim should be interpreted according to the meaning supplied by the inventor. *Markman*, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

The patents in-suit are generally directed to fluticasone furoate, which is a glucocorticoid drug compound used for its anti-inflammatory properties. The compound exists in three polymorphic forms: Form 1, Form 2, or Form 3. '866 Patent at 9:56-60. The forms "may be distinguished by means of X-Ray Powder Diffraction (XRPD)." *Id.* at 9:53-57. During XRPD, X-rays interact with the crystalline structure of a test sample and produce a "diffraction pattern." These patterns reveal "peaks" at various positions in a graph measured in "degrees [of] 2Theta." *Id.* The three forms of the patents are distinguished by the positions of their peaks in the graph.

See id. at 9:56-60.[1] "About around" is used in the claims in relation to the location of a peak on the graph. For example, "at around" is used as follows in claim 3 of the '866 Patent: "A compound of formula (I) in unsolvated form in the form of Form 1 polymorph, said Form 1 polymorph characterized by an XPRD profile having a peak **at around** 18.9 degrees 2Theta."[2]

The claim chart follows:

Term	GSK Proposed Construction	Sandoz Proposed Construction	Construction of the Court
"at around" (as used in claim 3 of the '866 Patent, and as used in the agreed construction of "Form 1" which applies to claims 1 and 5 of the '350 Patent, claim 20 of the '596 Patent, and claims 24 and 25 of the '866 Patent)	Ordinary meaning (no construction necessary)	"within a range of ±.1 degrees 2Theta"	"within a range of ±.1 degrees 2Theta"

Sandoz argues that "at around" indicates a well-established margin of error in the XRPD context, and this margin of error is no greater than ±.1 degrees 2Theta. GSK's brief argued that "at around" is an intentionally used word of approximation that needs no construction and that an individual skilled in the art is capable of determining whether a form has a peak of "at around" a certain 2Theta degree location. At oral argument, however GSK conceded that the patentee intended the "at around" language to account for the acceptable margin of error intrinsic to the XRPD measuring process. (D.I. 53, p. 52). GSK still maintains that a margin of error of ± .10

[1] Form 1's peak is measured at around 18.9 degrees 2Theta, Form 2's peaks are measured at around 18.4 and 21.5 degrees 2Theta, and Form 3's peaks are measured at around 18.6 and 19.2 degrees 2Theta.

[2] An XRPD profile having a peak at around 18.9 degrees 2Theta is also known as "Form 1" within the patent.

degrees 2Theta is too restrictive, and that a person skilled in the art would be capable of determining the margin of error with reference to the patent. Thus, the dispute crystallized to whether the margin of error may exceed ±.10 degrees 2Theta.

The Court agrees with Sandoz. The intrinsic and extrinsic evidence strongly suggests that an XRPD margin of error is no greater than ±.10 degrees 2Theta. To begin, the specification teaches that peak locations separated by .2 degrees are reliably distinguishable. This implies that .2 degrees is outside the margin of error; otherwise, the distinct peaks could not be differentiated. Further, the specification teaches that the "shifting leftward" of a peak location by .2 degrees is "particularly noticeable:"

> In the conversion of Form 3 to Form 2 the division of one peak in the range 21-23 degrees 2Theta into two peaks within the same range and the shifting leftwards of the peak at around 18.6 degrees 2Theta to around 18.4 degrees 2Theta are particularly noticeable.

See '866 Patent at 10:13-18. For a difference in peak location of .2 degrees to be particularly noticeable, the margin of error must be considerably less than .2 degrees. It would otherwise not be possible to tell with certainty whether the peak in fact shifted or whether the difference in location was merely a consequence of measuring error. This is all consistent with the margin of error equaling ±.10 degrees 2Theta.

GSK counters that the specification does not merely state that the peak "changes" from 18.6 to 18.4 in the conversion of Form 3 to Form 2, but that the peak is "shifting leftwards." According to GSK, it is this shifting that is particularly noticeable, not the location of the peaks, and the shifting would be apparent with a margin of error exceeding ±.1 degrees. GSK, however, fails to adequately explain why a peak's "shifting" in location would be more easily observed than a peak's "change" in location. Regardless of whether a peak location shifts or

changes, its beginning and ending points must be measured. Here, the difference between those two points is .2 degrees, and that difference is designated as "particularly noticeable" by the patent. This strongly suggests that the margin of error is significantly less than this amount, which is consistent with Sandoz's proposal of a ±.1 degrees margin of error.

GSK points out that forms are not solely distinguished by peak location, and thus a form may be identified even with a larger margin of error. This is true, but it is certain that peak location is a defining characteristic of a form, and identifying a form can depend at least in part on distinguishing peak location. GSK further argues that because Form 3 has two peaks, it would be possible to distinguish that form even if the margin of error was greater than ±.10 degrees. This argument fails to recognize that regardless of whether Form 3 in fact has two peaks, it still has a peak of 18.6 degrees that is recognized as a "particularly noticeable" difference from a peak of 18.4 degrees. For these reasons, the Court interprets the intrinsic evidence as supporting finding the margin of error as ±.10 degrees.

This brings the Court to the extrinsic evidence. The parties debate the significance of the following passage from the U.S. Pharmacopeia, which details the typical margin of error for XRPD measurement. The U.S. Pharmacopeia states that peak position "values should typically be reproducible to ±.10 or .20 degrees." (D.I. 52, J.A. 2 at Exh. B, p. 2007). The parties disagree as to the significance of the Pharmacopeia's providing two numerical values. Sandoz argues that the treatise intends to describe a margin of error of ±.10 degrees, which also may be understood to constitute a total variation of .20 degrees. GSK argues that this passage should be interpreted as allowing for two acceptable margins of error, i.e., ±.10 or ±.20 degrees 2Theta.

The Court agrees with Sandoz. The U.S. Pharmacopeia is an authoritative scientific treatise, and it makes most sense for the tome to provide only a single margin of error with regard to a measuring technique used in a field dependent on precision. Understanding "±.10 or .20 degrees" to provide a singular margin of error results in an internally consistent, if redundant, interpretation. On the other hand, adopting GSK's interpretation would result in inconsistency, as the Pharmacopeia would offer contradictory margins of error in the same breath, with one twice as large as the other. It is exceedingly unlikely that the treatise was authored to have two different margins of error. This finding is consistent with another district court's interpretation of the same passage. *See Abbott Laboratories v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 772 (N.D. Ill. 2007). Sandoz further cites numerous publications supporting finding a margin of error of ±.10 degrees. (*See* D.I. 52, J.A. 1 at ¶¶13, 15, 20). GSK's expert was unable to cite a single technical treatise or publication indicating an XRPD margin of error greater than ± .10 degrees, and the Court considers this absence of extrinsic evidence revealing as to the weakness of GSK's position.

For all these reasons, "at around" is construed as "within a range of ±.1 degrees 2Theta."